DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Rockville MD 20857

November 24, 1999

Jess H. Stribling
Ellen Armentrout
King & Spalding
1730 Pennsylvania Avenue, NW
Washington, DC 20006

Dear Mr. Stribling and Ms. Armentrout:

Your petition requesting the Food and Drug Administration to determine that a drug product containing 9.25 mg oxycodone hydrochloride, 0.85 oxycodone terephthalate, and 650 mg acetaminophen, and a drug product containing 7.0 mg oxycodone hydrochloride, 0.57 mg oxycodone terephthalate, and 500 mg acetaminophen in a tablet for a oral administration are a suitable for evaluation under ANDA was received by this office on November 19, 1999. It was assigned docket number 99P-5105/CP 1 and it was filed on November 23, 1999. Please refer to this docket number in future correspondence on this subject with the Agency.

Please note that the acceptance of the petition for filing is a procedural matter in that it in no way reflects an agency decision on the substantive merits of the petition.

Sincerely,

Lyle D. Jaffe
Dockets Management Branch

99P-5105

ACK 1